

## **REMARKS**

### **I. THE ELECTION OF SPECIES**

Applicants acknowledge the election of species in claim 2.

### **II. THE REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejects claims 1, 2 and 12-15 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 4,716,203 to Casey. The Office Action recognizes that Casey does not disclose polymers having the claimed molecular weights. The Office Action asserts, however, that it would have been obvious to one skilled in the art to determine suitable polymer weight through routine experimentation to obtain the best possible results. Applicants respectfully traverse the rejection.

The claimed invention is directed to diblock copolymers which are able to form stable micellar solutions and which are able to incorporate drugs without the need of complex incorporation techniques such as for example the use of organic solvents, followed by evaporation, or the use of dialysis. The claimed diblock copolymers are characterized by a hydrophilic part which has a specified molecular weight, namely < 1,000.

Since, the claimed copolymers have self-emulsifying properties and are therefore able to form spontaneously micellar solutions in water, there must be a good balance between the hydrophilic and the hydrophobic part of the diblock copolymers. This implies that the hydrophobic part of the copolymers has a relatively specified molecular weight, therefore, the copolymers are characterized by being liquid below 50°C.

It has been found that notwithstanding the fact that (1) the hydrophilic part of the copolymers is relatively small and (2) the total weight of the copolymers is relatively small, they are still able to form stable micelles.

One skilled in the art could not have predicted that such relatively small copolymers would be able to form stable micelles based on the disclosure of Casey. Moreover, one skilled in the art would not have been able to predict that micelles formed from such "small" copolymers could still incorporate drugs. Furthermore, one skilled in the art could not have predicted that the copolymers could very easily incorporate drugs, i.e., without the need to use complex techniques such as solvent evaporation or dialysis.

Casey does not disclose or suggest that the block copolymers disclosed therein have self-emulsifying properties that can form spontaneously stable micellar solution in water and thereby enhance the solubility of the active ingredients. There is no disclosure on these properties and hence, a skilled person looking for copolymers with these properties would not be motivated to take Casey into account since the reference is completely silent on such properties. Instead, the block copolymers of Casey are described as useful for coatings and lubricating finish for surgical material including sutures or for preparing degradable thermoplastic hydrogels thereof.

Furthermore, the Office Action asserts that Casey discloses diblock copolymers being liquid at a temperature below 50°C or below 37°C, citing column 2, lines 23-26. Casey discloses merely the viscosity of a 0.5 % solution of the copolymer in chloroform or methylene chloride, not that the copolymer is itself liquid.

Reconsideration and withdrawal of the rejection of claims 1, 2 and 12-15 under 35 U.S.C. § 103 over Casey are respectfully requested.

### III. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

/Laura A. Donnelly/

By: \_\_\_\_\_  
Laura A. Donnelly  
Reg. No. 38,435

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1729  
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